UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RANBAXY LABORATORIES LIMITED, et al.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 04-0133 (PLF)
UNITED STATES FOOD & DRUG ADMINISTRATION, et al.,	)	
Defendants,	)	
and	)	
PFIZER INC.,	)	
Defendant-Intervenor.	)	

OPINION

This matter initially came before the Court on plaintiffs' motion for a preliminary injunction. At filing, plaintiffs Ranbaxy Laboratories Limited, Ranbaxy Inc. and Ranbaxy Pharmaceuticals, Inc. (collectively, "plaintiffs" or "Ranbaxy") also moved for summary judgment and to consolidate the preliminary injunction hearing with a hearing on the merits. The federal defendants, the United States Food and Drug Administration; Mark B. McClellan, M.D., Ph.D., Commissioner of the Food and Drug Administration; and Tommy G. Thompson, Secretary, United States Department of Health and Human Services (collectively, the "Federal Defendants" or "FDA") filed an opposition to the motion for a preliminary injunction and a cross-motion for summary judgment. Defendant-intervenor Pfizer Inc. ("Pfizer") also filed a cross-motion for summary judgment and an opposition to both of plaintiffs' motions.

Oral argument on the motions took place on March 4, 2004. All the parties requested that the Court expedite its decision so that an appeal may be taken promptly in light of the time-sensitive nature of the matter.

I. BACKGROUND

A. *Statutory Background*

Broadly, this matter concerns the process by which the FDA approves generic drugs, which is delineated in a 1984 amendment to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., commonly referred to as the "Hatch-Waxman Amendments." See 21 U.S.C. § 355(j). This matter also concerns a second amendment to the FDCA that provides for an additional exclusivity period for patents held by brand-name drug manufacturers that participate in pediatric studies of those patented drugs. See 21 U.S.C. § 355a. Both these statutory schemes are explained in great detail in Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998), and Barr Laboratories, Inc. v. Thompson, 238 F. Supp. 2d 236, 239-241 (D.D.C. 2002). There is no need to recite their background again here.

B. *Administrative History of this Action*

On January 29, 1990, the FDA approved Pfizer's new drug application ("NDA") for fluconazole (brand name Diflucan), which is indicated for the treatment of various fungal infections, including vaginal yeast infections, oral yeast infections and cryptococcal meningitis. See Complaint ("Compl."), Ex. 1, *Physicians' Desk Reference* 2592 (58th ed. 2004) at 3. Pfizer filed patents that claim Pfizer's approved drug product and uses, and the FDA listed these patents in the "Approved Drug Products With Therapeutic Equivalence Evaluations" listing ("Orange

Book"). U.S. Patent No. 4, 404,216 ("'216 Patent"), the last of the Pfizer patents at issue in this matter, expired on January 29, 2004. See Compl., Ex. 2, Orange Book Excerpt at 3.

Ranbaxy, a generic drug manufacturer, submitted to the FDA an abbreviated new drug application ("ANDA") for fluconazole (oral suspension) on December 26, 2001, and an ANDA for fluconazole (tablet) on March 27, 2002. See Compl., Ex. 3, July 11, 2003, Letter from Gary Buehler, Director, Office of Generic Drugs to Abha Pant, U.S. Agent for Ranbaxy Laboratories, Ltd. (oral suspension) ("July 11, 2003 FDA Letter"); Compl., Ex. 4, May 1, 2003, Letter from Gary Buehler, Director, Office of Generic Drugs to Abha Pant, U.S. Agent for Ranbaxy Laboratories, Ltd. (tablet) ("May 2, 2003 FDA Letter").[1] Each ANDA contained a Paragraph IV certification to the '216 Patent. Ranbaxy provided notice of the certifications to Pfizer in accordance with Section 505(j)(2)(B), and in response Pfizer filed a patent infringement suit on each ANDA within the 45-day period provided for in the statute in the United States District Court for the District of New Jersey. These filings triggered a 30-month statutory stay. The district court subsequently consolidated the two suits. During the course of the litigation the FDA tentatively approved both of Ranbaxy's ANDAs. See July 11, 2003 FDA Letter; May 2, 2003 FDA Letter.

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[1] Along with its ANDA, an ANDA applicant must submit a certification with respect to any patents covering the brand-name drug. Such certification must reflect the applicant's conclusion (1) that the required patent information related to such a patent has not been filed ("Paragraph I certification"); (2) that such patent has expired ("Paragraph II certification"); (3) the date on which such patent will expire ("Paragraph III certification"); or (4) that such patent is invalid or will not be infringed by the ANDA's proposed generic product ("Paragraph IV certification"). 21 U.S.C. §355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.95. The FDA requires an ANDA applicant to amend its certification "if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate." 21 C.F.R. § 314.94(a)(12)(viii)(C)(1).

Also during the course of the patent infringement litigation, the district court denied Pfizer's motion for summary judgment. See Administrative Record ("AR"), Ex. 30, December 26, 2003 Letter from Abha Pant to Gary J. Buehler ("December 26, 2003 FDA Letter") at 1 and attached court docket. After the summary judgment decision, however, the court indicated to Ranbaxy and Pfizer that the court's schedule would not allow for a trial until after the January 29, 2004, expiration of the '216 Patent. See December 26, 2003 FDA Letter at 2. In response, the parties entered into a stipulation of dismissal on November 14, 2003. See Compl., Ex. 9, Pfizer Inc. v. Ranbaxy Pharmaceuticals, Inc., Consolidated Civil Action No. 02-2493 (GEB), Stipulation of Dismissal (D.N.J. Nov. 14, 2003). The Stipulation provided that in light of the fact that the '216 Patent was set to expire prior to the time that the court's schedule could accommodate a trial, the consolidated actions would be "dismissed as moot upon the January 29, 2004 expiration of the '216 patent with no further action of the parties, with each party to bear its own costs and attorneys' fees." Id. at 1.

Meanwhile, on December 31, 2001, the FDA had issued a written request to Pfizer for pediatric studies on fluconazole, and Pfizer submitted the requisite studies in response. On January 21, 2004, the FDA determined that Pfizer's pediatric studies adequately responded to the written request, and concluded that Pfizer was entitled to pediatric exclusivity for fluconazole under Section 505a. See AR, Ex. 32, Pediatric Exclusivity Determination Checklist (granting pediatric exclusivity). In response to the threat of a pediatric exclusivity grant to Pfizer that would preclude the final approval of Ranbaxy's ANDAs, Ranbaxy sought confirmation with the FDA by letters of June 6, 2003, August 21, 2003, and January 16, 2004, that its fluconazole ANDAs would be approved upon expiration of the '216 Patent on January 29, 2004. In each

letter Ranbaxy asserted that the preconditions for delaying an ANDA on the basis of pediatric exclusivity provided for in Section 505a(c)(2)(B) (governing Paragraph IV certifications) could not be satisfied unless Pfizer obtained a ruling that the '216 Patent was valid and would be infringed, which it was unlikely to do in view of the district court's schedule. See AR, Ex. 26, June 6, 2003 Letter from Abha Pant to Gary J. Buehler; AR, Ex. 28, August 21, 2003 Letter from David G. Adams, Esq. to Daniel E. Troy, Chief Counsel Food and Drug Administration; AR, Ex. 31, January 16, 2004 Letter from Richard M. Cooper, Esq. to Daniel E. Troy.

By letter of January 28, 2004, the FDA issued an administrative decision indicating that Ranbaxy's ANDAs would not be approved until after the expiration of Pfizer's pediatric exclusivity on July 29, 2004. In the decision, the FDA concluded that "an ANDA applicant will be subject to any pediatric exclusivity that attaches to a patent where the ANDA applicant has filed a paragraph IV certification, was sued by the NDA holder or patent owner within 45 days, and the litigation is unresolved on the merits and the 30-month stay has not run when the patent expires." AR, Ex. 34, January 28, 2004 Letter from Gary J. Buehler to Richard M. Cooper ("FDA Ranbaxy Decision"). In so concluding, the FDA first determined that Ranbaxy had relied on the wrong subsection of the pediatric exclusivity statute because the generic manufacturer wrongly had assumed that its Paragraph IV certification remained in effect past the expiration of the patent. See id. at 4. Instead, the FDA decided that upon patent expiry, the Paragraph IV certification became a Paragraph II certification (irrespective of Ranbaxy's failure to amend its certification to reflect the change in each patent's status under 21 C.F.R.

§ 314.94(a)(12)(viii)(C)(1)) and that under a Paragraph II certification, the statute provides for a delayed ANDA approval for six months beyond expiration of the patent. See id. at 4-5.[2]

The FDA then opined that even if Section 505a(c)(2)(B) were the applicable subsection for the purpose of determining Pfizer's pediatric exclusivity, the subsection does not address expressly a situation in which the patent litigation is unresolved at the time of patent expiry. Assuming its duty to fill gaps left in the statute by Congress, the FDA concluded that the absence of a provision addressing unresolved patent litigations in the Paragraph IV certification context did not mean that Congress intended to exclude such circumstances from the pediatric exclusivity provision. See FDA Ranbaxy Decision at 5-6. This alternative reading, the FDA concluded, would undercut the purpose of pediatric exclusivity and invite anomalies and manipulation of the statute. See id. at 6-7.

C. *Summary of the Parties' Arguments on the Merits*

Ranbaxy's summary judgment argument can be summarized as follows: Ranbaxy held an ANDA with a Paragraph IV certification until midnight on January 29, 2004, at which time the '216 Patent expired and the Stipulation of Dismissal came into effect. This event lifted the 30-month stay and, at that "magic moment," the ANDAs automatically gained, or were entitled to gain, immediate effective final approval. This is so because the patent

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[2] The FDA rejected Ranbaxy's underlying premise that because Ranbaxy had received tentative approval of its ANDAs, the generic manufacturer was entitled as a matter of law to full approval the instant the patent expired, and that as an approved ANDA, the Paragraph IV certification could not have been converted to a Paragraph II certification. In support of its decision, the FDA cited instances in which a tentatively-approved ANDA did not receive automatic final approval notwithstanding patent expiry. The FDA also rejected Ranbaxy's argument that final approval should be made effective *nunc pro tunc* as of January 29, 2004, citing a lack of FDA precedent to that effect. See FDA Ranbaxy Decision at 5.

litigation became moot at the very instant the patent expired and the statutory stay terminated. Ranbaxy argues in the alternative that if the ANDAs did not obtain final approval automatically upon the dismissal of the suit and the lifting of the stay, approval should have been granted *nunc pro tunc* back to that date. Turning to the pediatric exclusivity issue, Ranbaxy asserts that having maintained a Paragraph IV certification up to the time of approval on January 29, 2004, the only applicable section of the pediatric exclusivity provision was Section 505a(c)(2)(B) (concerning Paragraph IV certifications). Under that subsection, Ranbaxy argues, the only circumstance in which the pediatric exclusivity protections delay an ANDA holder's entry into the market is when the court in the underlying patent infringement litigation has determined that the patent was valid and would be infringed. Here, there was no such determination, and therefore Pfizer's pediatric exclusivity does not preclude Ranbaxy from entering the market.

The Federal Defendants counter that Ranbaxy's ANDAs only had tentative approval as of January 29, 2004, and that there is no automatic or *nunc pro tunc* final approval provided to ANDAs when litigation ends and the 30-month stay is lifted. Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform, and an applicant has no vested right to enter the market until the FDA gives its final formal approval. Defendants argue that the critical event that occurred on January 29, 2004, was not the lifting of the stay, but the expiration of the patent. As a result of the patent expiration, Ranbaxy's ANDAs became invalid. Either the applications with their Paragraph IV certifications automatically converted to Paragraph II certifications upon

expiration of the patent, or Ranbaxy was required to amend them in order to reflect the patent expiry because the Paragraph IV certifications were no longer accurate.

More specifically, the Federal Defendants maintain, a Paragraph IV certification states that, in the applicant's view, the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A Paragraph II certification states that "such patent has expired." 21 U.S.C. § 355(j)(2)(A)(vii)(II). Section 505(j) provides that an ANDA that contains an untrue statement of material fact cannot be approved. See 21 U.S.C. § 355(j)(4)(K). Therefore, at the "magic moment" of midnight on January 29, 2004, Ranbaxy's Paragraph IV certification was no longer accurate and no longer valid because the patent to which it related had expired. The Paragraph IV certification either became a Paragraph II certification, or FDA was entitled to treat it as a Paragraph II certification, because the patent had expired. Alternatively, Ranbaxy was required to amend the Paragraph IV certification to provide accurate information, namely, the expiration of the patent, the lack of which made the Paragraph IV certification invalid and non-approvable and left as the only option available a Paragraph II certification. Turning to the pediatric exclusivity provisions of the statute, the Federal Defendants argue that once the patent had expired, Section 505a(c)(2)(A)(i) (governing Paragraph II certifications) applies, and that under the subsection, the ANDAs are subject to a delay in approval of six months.[3]

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[3] The Federal Defendants also argue that even if Section 505a(c)(2)(B) (governing Paragraph IV certifications) were applicable to Ranbaxy's ANDAs, the provision is ambiguous as to its applicability to the facts of this case because it only expressly addresses exclusivity when there is a finding of validity and infringement. Because it is ambiguous, the FDA's decision to delay approval of Ranbaxy's ANDAs under the pediatric exclusivity provisions is owed deference and should be upheld.

II. DISCUSSION

A. *Proper Standard of Review*

Plaintiffs assert that because the FDA Ranbaxy Decision is an opinion letter and not the product of a formal deliberative process, it is entitled to careful consideration under Skidmore v. Swift & Co., 323 U.S. 134 (1944), but not to deference under Chevron U.S.A. Inc. v. National Resources Defense Council, Inc., 467 U.S. 837 (1984). See Plaintiffs' Memorandum in Opposition to Federal Defendants' Cross-motion for Summary Judgment and Memorandum in Reply to Plaintiffs' Motion for Preliminary Declaratory and Injunctive Relief, to Consolidate the Preliminary Relief Hearing with the Summary Judgment Hearing or the Trial on the Merits, and for Summary Judgment Granting Final Declaratory and Injunctive Relief at 4-5. The Federal Defendants respond that the FDA Ranbaxy Decision must be reviewed under the deferential Chevron standard, and thus may be set aside under the Administrative Procedure Act only if that decision was arbitrary and capricious, not in accordance with the law, or unwarranted by the facts. See Federal Defendants' Memorandum in Opposition to Plaintiffs' Motion for a Preliminary Injunction and Summary Judgment and in Support of Cross-Motion for Summary Judgment ("Defs.' Mem.") at 16-17 (citing 5 U.S.C. § 706(2)(A)). The Court does not reach this question, however, because under either standard,

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Pfizer offers additional arguments in favor of delaying Ranbaxy's ANDAs' approval period for the 6-month pediatric exclusivity period. See Memorandum of Points and Authorities of Pfizer Inc. in Opposition to the Motion of Ranbaxy Laboratories Limited, Ranbaxy Inc., and Ranbaxy Pharmaceutical, Inc. for Declaratory and Injunctive Relief and in Support of Defendant's Motion for Summary Judgment. Plaintiffs responded to Pfizer's arguments asserting, *inter alia*, that the Court may not consider any basis for upholding the Ranbaxy Decision Letter on which the FDA itself did not rely in its administrative decision.

the Court concludes that the Federal Defendants' reading of the relevant provisions of the FDCA is the correct one, and that they therefore are entitled to summary judgment as a matter of law.

B. *Summary Judgment in Favor of Defendants*

The Court agrees with the Federal Defendants in this matter. In light of the parties' request for an expedited review, however, and of the fact that the issues before the Court raise solely questions of law that will be reviewed *de novo* by the court of appeals using the same standard applied here, the Court will not issue a detailed opinion. It is enough to say that the Court largely agrees with the positions of the Federal Defendants as summarized in Section I(C), *supra*.[4] The Court concludes that under the FDCA final approval of Ranbaxy's ANDA's did not automatically take place upon the dismissal of the underlying patent litigation, the expiration of the patent and the lifting of the "30 month" stay. Nor is *nunc pro tunc* final approval available to Ranbaxy under the statute. Rather, at that "magic moment," midnight on January 29, 2004, the Paragraph IV certifications became invalid, and either converted as a matter of law to Paragraph II certifications or became inaccurate, thereby creating both an obligation on Ranbaxy's part to amend its ANDAs to reflect patent expiry and an inability on the part of the FDA to approve the ANDAs in their inaccurate form. Under either scenario, the applicable provision of Section 505a became 505a(c)(2)(A)(i), and, under that provision, approval of Ranbaxy's ANDAs is delayed six months until July 29, 2004. See Defs.' Mem. at 20, 26-28, 30-32; Federal Defendants' Reply Memorandum in Support of Cross-Motion for Summary Judgment at 8-16. Accordingly, the Court will grant the Federal Defendants' motion

[4] The Court does not endorse the arguments of either the FDA or Pfizer that are summarized in Note 3, *supra*.

for summary judgment, will grant Pfizer's motion for summary judgment, and will deny plaintiffs' motion for summary judgment. The Court will deny as moot plaintiffs' motion for a preliminary injunction. A separate Order consistent with this Opinion shall issue this same day.

SO ORDERED.

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PAUL L. FRIEDMAN
United States District Judge

DATE:

UNITED STATES DISTRICT COURT
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Defendants,	)	
and	)	
PFIZER INC.,	)	
Defendant-Intervenor.	)	

ORDER AND JUDGMENT

For the reasons stated by separate Opinion issued this same day, it is hereby

ORDERED that Plaintiffs' Motion for Preliminary Declaratory and Injunctive Relief, to Consolidate the Preliminary Relief Hearing with the Summary Judgment Hearing or the Trial on the Merits, and for Summary Judgment Granting Final Declaratory and Injunctive Relief [2-1] is GRANTED in part and DENIED in part; it is

FURTHER ORDERED that plaintiffs' motion for preliminary declaratory and injunctive relief is DENIED as moot; it is

FURTHER ORDERED that plaintiffs' motion to consolidate the preliminary relief hearing with the summary judgment hearing is GRANTED; it is

FURTHER ORDERED that plaintiffs' motion for summary judgment is DENIED; it is

FURTHER ORDERED that Federal Defendants' Cross-Motion for Summary Judgment [10-1] is GRANTED; it is

FURTHER ORDERED that JUDGMENT is entered for the United States Food and Drug Administration; Mark B. McClellan, M.D., Ph.D., Commissioner of the Food and Drug Administration; and Tommy G. Thompson, Secretary, United States Department of Health and Human Services; it is

FURTHER ORDERED that Pfizer's Cross-Motion for Summary Judgment [13-1] is GRANTED; it is

FURTHER ORDERED that JUDGMENT is entered for Pfizer Inc.; it is

FURTHER ORDERED that this case is DISMISSED from the docket of this Court; and it is

FURTHER ORDERED that this Order and Judgment shall constitute a FINAL JUDGMENT in this case. This is a final appealable order. See FED. R. APP. P. 4(a).

SO ORDERED.

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PAUL L. FRIEDMAN
United States District Judge

DATE: